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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,411	10/22/2003	Vince Pozsgay	4239-67013	8496

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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/692,411

Applicant(s)

POZSGAY, VINCE

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-22, 27, 32, 37, 42, 43 and 48-53 is/are pending in the application.
- 4a) Of the above claim(s) 27, 32, 37, 42, 43 and 48-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/22/03</u> . | 6) <input type="checkbox"/> Other: _____  |

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**1)** Applicant is advised that the Garner reference cited on form PTO-1449 (dated October 22, 2003) is not present in the file of the parent application nor in the file of this application and has not been considered by the examiner when preparing this Office action.

**2)** Claims 27, 32, 37, 42, 43 and 48-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in the reply filed on April 13, 2006.

**3)** The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**4)** Claims 16-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of conjugates corresponding to the second structure depicted in claim 16 (referred to as **2**) wherein B<sub>1</sub> is a sugar moiety, does not reasonably provide enablement for the preparation of conjugates **2** wherein B<sub>1</sub> is any other moiety or for conjugates which correspond to the first structure depicted in claim 16 (referred to as **1**). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. For example, the specification provides no enabling description for how to attach the moieties B<sub>1</sub> and B<sub>2</sub> to the cyclohexene ring structure of conjugate **1**. Enablement for the preparation of the claimed conjugates is limited to the use of the diene-functionalized sugar reactants depicted by structures **8**, **27** and **32** of the specification in combination with a maleimide-based dienophile; this method prepares conjugates wherein B<sub>1</sub> is attached at the ring position

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*which contains either the moiety R or R<sup>1</sup> as shown in conjugate 2 of claim 16* (see for example, structures **12**, **15** and **21** of the specification) and does not produce the conjugate **2** of claim 16 wherein B<sub>1</sub> is attached at a ring position other than the positions which contain R and R<sup>1</sup>.

**5)** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**6)** Claims 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**a)** In claim 16, it is unclear what is meant by the term "B<sub>1</sub> and B<sub>2</sub>...are optionally attached via a linker". The term could have two meanings: either B<sub>1</sub> and B<sub>2</sub> are attached to each other via a linker or each is attached to the cyclohexene ring via a linker.

**b)** In claim 16, it is unclear where the moieties B<sub>1</sub> and B<sub>2</sub> are attached to the cyclohexene ring of structure **1** and where the moiety B<sub>1</sub> is attached to the cyclohexene ring of structure **2**. See the discussion of paragraph **4)** above with regard to the discrepancy between the description of the conjugates prepared by the method described in the specification and the structures depicted in the claims.

**7)** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**8)** Claims 16-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Pieken et al {WO 98/30575}.

Pieken et al describe the cycloaddition reaction of diene-functionalized biomolecules with dienophile-functionalized biomolecules to prepare biomolecules conjugates which anticipate the conjugates of claim 16. See page 23, lines 14-28; page 26, lines 7-14; (as recited in claims 16 and 21 of this application) biomolecules may be nucleic acids, peptides, proteins, carbohydrates, polysaccharides and solid supports: page 13, lines 4-15; SCHEME 22; SCHEME 28. For the "pharmaceutical composition" of claim 22 further comprising "a pharmaceutically acceptable carrier", see the "aqueous media" of page 23, lines 21-23 of Pieken et al which can be considered to be "a pharmaceutically acceptable carrier".

**9)** Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Perbost {US 6,171,979}. Perbost describes biomolecule/solid phase conjugates prepared by the cycloaddition reaction of a diene or dienophile-functionalized solid phase with the corresponding diene-functionalized biomolecule; these conjugates anticipate the conjugates of claim 21. See col. 4, line 52 – col. 5, line 6; col. 3, lines 41-53; col. 7, lines 3-7 (biomolecules defined as peptides, nucleic acids and polysaccharides).

**10)** Claim 16 is rejected under 35 U.S.C. 102(a) as being anticipated by Picken {WO 00/31102}.

Picken describes conjugates prepared by the reaction of a diene-functionalized oligonucleotide with a dienophile-functionalized peptide to form oligonucleotide/peptide conjugates which anticipate the

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first structure of claim 16 of this application (conjugate **1**). See the reaction scheme of page 27; Figure 1.

**11)** Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Picken et al {US 5874,532}.


Structures **42** and **44** of SCHEME 10 (cols. 51 and 52) of Picken et al depict solid support/oligonucleotide conjugates which anticipate the conjugates shown in the second structure of claim 21 of this application.

**12)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 22, 2006

  
Mary (Molly) E. Ceperley  
Primary Examiner  
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